The following corrections or additions to the January 2004 list were published in the Federal Register in May 2004.

New Approvals

ANADA Number: 200-341

Pioneer Product:	140-439
Trade Name:	SparMectin-E
Ingredients:	Ivermectin
Sponsor:	Veterinary Laboratories, Inc.
Approval Date:	March 8, 2004
Status:	Prescription only
Route:	Oral drench or stomach tube (nasogastric intubation)
Species:	Horses
Drug Form:	Liquid
Concentration:	10 milligrams per milliliter
Indications:	For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, largemouth stomach worms, bots, lungworms and summer sores. Also treats cutaneous onchocerciasis.

21CFR 520.1195

ANADA Number: 200-359

Pioneer Product:	141-147
Trade Name:	Pennchlor™ / Deccox®
Ingredients:	Chlortetracycline, decoquinate
Sponsor:	Pennfield Oil Compnay
Approval Date:	March 19, 2004
Status:	Over-the-counter
Route:	Oral
Species:	Calves, beef and non-lactating dairy cattle
Drug Form:	Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration:	Chlortetracycline – 50 to 100 grams activity per pound of Type A Medicated Article; Decoquinate – 27.2 grams activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* for the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.
Tolerance:	*21CFR 556.150* Chlortetracycline: The established tolerances for the sum of residues of the tetracyclines, including chlortetracycline, in tissues is 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney. *21CFR 556.170* Decoquinate: The established tolerance for residues of decoquinate in the uncooked edible tissues are 1 part per million in skeletal muscle and 2 parts per million in other tissues.
Withdrawal:	One day

21CFR 558.195

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-236

Trade Name:	Vetsulin™
Ingredients:	Porcine insulin zinc
Sponsor:	Intervet, Inc.
Approval Date:	April 1, 2004
Status:	Prescription only
Route:	Subcutaneous
Species:	Dog
Drug Form:	Liquid (suspension)
Concentration:	40 international units (IU) per milliliter
Indications:	For the reduction of hyperglycemia and hyperglycemia associated clinical signs with diabetes mellitus.
Exclusivity:	5 years

21CFR 522.1160

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to *21CFR Parts 500* and the related Federal Register notices.

NADA Number: 141-087

This supplemental application provides for the treatment and control of an additional species of small strongyles (*Coronocyclus labratus*) and for the speciation of adult small strongyles in the product labeling.

Trade Name:	Quest® Gel
Ingredients:	Moxidectin
Sponsor:	Fort Dodge Animal Health Division of Wyeth
Approval Date:	March 17, 2004
Status:	Over-the-counter
Route:	Oral
Species:	Horses and ponies
Drug Form:	Gel
Concentration:	20 milligrams per milliliter
Indications:	For the treatment and control of the following stages of gastrointestinal parasites of horses and ponies six months of age and older which will not to be used for food: **Large strongyles**: *Strongylus vulgaris* (adult and L4/L5 arterial stages), *Strongylus edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), *Triodontophorus serratus* (adults) **Small strongyles** (adults): *Cyathostomum spp*. including *C. catinatum*, *C. pateratum*; *Cylicocyclus spp*. including *C. insigne*, *C. leptostomum, C. nassatus; Cylicostephanus spp*. including *C.calicatus, C. goldi, C. longibursatus*, *C. minutis; Coronocyclus spp.,* including *C. coronatus, C. labiatus, C. labratus*; *Gyalocephalus capitatus*; undifferentiated luminal larvae **Encysted cyathostomes**: late L3 and L4 mucosal cyathostome larvae **Ascarids**: *Parascaris equorum* (adults and L4 larval stages) **Pinworms**: *Oxyuris equi* (adults and L4 larval stages) **Hairworms**: *Trichostrongylus axei* (adults) **Large-mouth stomach worms**: *Habronema muscae* (adults) **Horse stomach bots**: *Gasterophilus intestinalis* (2nd and 3rd instars), *G. nasalis* (3rd instars) One dose also suppresses strongyles egg production for 84 days.
Patent Number:	4,916,154 Expiration date: April 10, 2007
Exclusivity:	3 years

21CFR 520.1452

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 008-804

This supplemental application provides for a zero day pre-slaughter withdrawal time in cattle administered oxytetracycline at 10 mg/lb body weight per day for 14 days.

Trade Name:	TM-50®, TM-50®D, TM-100®, TM-100®D Type A Medicated Articles
Ingredients:	Oxytetracycline (from oxytetracycline quaternary salt) equivalent to oxytetracycline hydrochloride
Sponsor:	Phibro Animal Health
Approval Date:	March 12, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle (beef cattle, non-lactating dairy cattle and calves including pre-ruminating veal calves).
Drug Form:	Type A Medicated Article.
Concentration:	50 or 100 grams per pound activity of Type A Medicated Article.
Indications:	For increased rate of weight gain and improved feed efficiency; reduction of liver abscesses; for prevention and treatment of the early stages of shipping fever complex; the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline.
Tolerance:	21CFR 556.500 Oxytetracycline: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney and 0.3 part per million in milk.
Withdrawal:	Cattle: zero days

21CFR 558.450

NADA Number: 095-143

This supplemental application provides for a zero day pre-slaughter withdrawal time in cattle administered oxytetracycline at 10 mg/lb body weight per day for 14 days.

Trade Name:	Terramycin® 50, Terramycin® 100, Terramycin® 200 Type A Medicated Articles
Ingredients:	Oxytetracycline
Sponsor:	Phibro Animal Health
Approval Date:	March 12, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle (beef cattle, non-lactating dairy cattle and calves including pre-ruminating veal calves).
Drug Form:	Type A Medicated Article to make Type C medicated feeds.
Concentration:	50, 100, or 200 grams per pound activity of Type A Medicated Article.
Indications:	For increased rate of weight gain and improved feed efficiency; reduction of liver abscesses; for prevention and treatment of the early stages of shipping fever complex; the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline.
Tolerance:	21CFR 556.500 Oxytetracycline: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of swine, as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal:	Cattle: zero days

21CFR 558.450

Removal of Patent

NADA Number: 141-199

Patent Number:	6,013,808
Expiration Date:	April 15, 2019

Actions Taken by FDA Center for Veterinary Medicine

Suitability Petition Action

Number:	04P-0197/CP1
Sponsor:	First Priority, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristic(s): The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.77 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.
Action:	Filed on April 26, 2004.

Number:	04P-0127/CP1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe®, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristic(s): The generic product will have a different dosage form (tablet) and different strength (concentration) from the pioneer.
Action:	Denied on May 11, 2004.

Number:	04P-0128/CP1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug amoxicillin trihydrate/clavulanate potassium which differs from the pioneer product, Clavamox® Tablets, Pfizer Inc., NADA 055-099 by the following characteristic(s): The generic product will have a different strength (concentration) from the pioneer.
Action:	Denied on May 13, 2004.

Number:	04P-0136/CP1
Sponsor:	Intervet Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug florfenicol which differs from the pioneer product, Nuflor®, Schering-Plough Animal Health Corp., NADA 141-063 by the following characteristic(s): The generic product will have a different strength (concentration) from the pioneer.
Action:	Approved on May 19, 2004.

Technical Amendment

The Food and Drug Administration (FDA) is revising the animal drug regulations for medicated feeds to reflect the approved maximum concentration of ractopamine in Type B medicated feeds. This action is being taken to improve the accuracy of the agency's regulations. FDA has found that parts 500 to 599 (21 CFR parts 500 to 599) of the Code of Federal Regulations does not reflect the approved maximum concentration of ractopamine in Type B medicated feeds. Higher levels of ractopamine in Type B medicated feeds were approved when this drug was approved for use in cattle on September 18, 2003 (68 FR 54658). At this time, FDA is amending the regulations in 21 CFR 558.4 to reflect the new maximum concentration of ractopamine (2.46 grams per pound) in Type B medicated feeds. This rule is effective May 6, 2004.

Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed

The Food and Drug Administration (FDA) is changing the regulations in sections 510.455, 558.5, 558.95, 558.305, 558.311, 558.342, 558.355, and 558.625, for liquid medicated feed and free-choice medicated feed. By changing the regulations for liquid medicated feed, FDA is clarifying the following: what data are required to demonstrate chemical and physical stability of a drug in liquid feed, how such data may be submitted for use in the new animal drug approval process, and which liquid medicated feeds may be manufactured in a feed manufacturing facility that has not obtained a medicated feed mill license from FDA. By changing the regulations for free-choice medicated feed, FDA is ensuring that they are consistent with the requirements for liquid medicated feed, and that provisions for free-choice medicated feed and liquid medicated feed comply with the terms of the Animal Drug Availability Act (ADAA) of 1996.